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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/035,845	12/24/2001	William H. Reeves	L-00003-004	4172

25179 7590 06/06/2003

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EXAMINER

FOREMAN, JONATHAN M

ART UNIT	PAPER NUMBER
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3736

DATE MAILED: 06/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/035,845

Applicant(s)

REEVES ET AL.

Examiner

Jonathan ML Foreman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1 - 18 is/are pending in the application.
- 4a) Of the above claim(s) 13 - 18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 - 12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Election/Restrictions*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1 - 12, drawn to an apparatus for identifying and monitoring women at risk of developing OSE-derive carcinomas, classified in class 600, subclass 562.
  - II. Claims 13 - 18, drawn to a method for identifying and monitoring women at risk of developing OSE-derived carcinomas, classified in class 128, subclass 898.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case an apparatus having a stylet must perform the process. Additionally, the apparatus can be used to perform a biopsy at a location other than the ovary of a patient.
3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.
4. Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II, restriction for examination purposes as indicated is proper.
5. During a telephone conversation with R. William Graham on 5/29/03 a provisional election was made without traverse to prosecute the invention of Group I, claims 1 - 12. Affirmation of this election must be made by applicant in replying to this Office action. Claims 13 – 18 are withdrawn

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from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### *Information Disclosure Statement*

The information disclosure statement filed 12/24/01 complies with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609. It has been placed in the application file, and the information referred to therein has been considered by the examiner as to the merits.

### *Specification*

7. The disclosure is objected to because of the following informalities: Line 22, Page 5 states “optic fiber 18”. The optic fiber has previously been referred to with reference numeral 28. On Page 7 in the 4<sup>th</sup> paragraph through the first full paragraph on Page 5, the microendoscope is referred to with reference numeral 26. The microendoscope has previously been referred to with reference numeral 23.

Appropriate correction is required.

### *Claim Objections*

8. Claim 1 is objected to because of the following informalities: line 3 begins with “includes”. Appropriate correction is required.

*Claim Rejections - 35 USC § 112*

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 5 – 8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

11. Claim 5 recites the limitation "said housing" in line 2. There is insufficient antecedent basis for this limitation in the claim.

*Claim Rejections - 35 USC § 103*

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. Claims 1 – 5 and 9 - 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application No. 2003/0083552 to Remijan et al. in view of U.S. Patent Application Publication No. 2002/0165467 to Rutenberg.

In reference to claims 1 – 5, and 9 -12, Remijan et al. discloses applicant's claimed invention including an introducer needle [0043], a microendoscope having an optic fiber (26) [0038] which is operably insertable into the needle [0047] in a manner to enable an image to be obtained therethrough. It has been held that the recitation that an element is "capable of" performing a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. *In re Hutchison*, 69 USPQ 138. In the present case the

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needle disclosed by Remijan et al. is capable of insertion into a female such that the terminal end of the needle is adjacent to the ovary. Remijan et al. discloses a stylet (80) extending through the needle to block material from entering the needle [0045]. The optic fiber disclosed by Remijan et al. extends out of an open connector surface (36) of a housing and has a length equal to the needle [0038][0041][0049]. The angled connection between the housing and the light source in figure one is considered by the examiner to be a v-shape. The microendoscope disclosed by Remijan et al. has a fiber optic light source (40) operably connected to the housing [0039] so that the fiber is illuminated. Remijan et al. discloses a flexible protective tubing (34)[0038] covering the optic fiber. Remijan discloses performing a procedure through the operative channel of the endoscope [0085] and discloses that such a procedure could be removing a gynecological tissue sample [0009], but fails to disclose a tissue removing member operably co-insertable into the needle for removal of tissue cells. Rutenberg teaches a cytological brush that passes through the operative channel in an endoscope to remove surface epithelial cells. Rutenberg teaches that the size of the brush and the structure of the brush can be varied [0044]. It would have been obvious to one having ordinary skill in the art to modify the microendoscope as disclosed by Remijan et al. to include a cytological brush as taught by Rutenberg in order to perform non-lacerational biopsies of the ovary.

14. Claims 6 – 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application No. 2003/0083552 to Remijan et al. in view of U.S. Patent Application Publication No. 2002/0165467 to Rutenberg as applied to claim 5 above, and further in view of U.S. Patent No. 5,873,814 to Adair.

In reference to claims 6 – 8, Remijan et al. in view of Rutenberg discloses a camera (30) being connected to a monitor (46) operably connected to a computer (44) having software to enable viewing of the image [0040]. However, Remijan et al. fails to disclose the monitor being a touch

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screen monitor, and the computer including a microphone and having voice recognition software associated with the microphone to permit notes to be recorded. Adair teaches an endoscopic video touch screen monitor (Col. 4, lines 36 – 42; lines 49 – 65) and a computer having a microphone and voice recognition software associated with the microphone to permit notes to be recorded (Col. 4, lines 58 – 65; Col. 8, lines 60 – 62). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the monitor and computer as disclosed by Remijan et al. in view of Rutenberg to be a touch screen monitor and to include a microphone and voice recognition software associated with the microphone in order to remove the need for a keyboard and allow the surgeon to control the endoscope and record data hands free.

### *Conclusion*

15. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. U.S. Patent No. 6,156,006 to Brosens et al. and U.S. Patent No. 6,405,074 to Banerjee

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan ML Foreman whose telephone number is (703)-305-5390. The examiner can normally be reached on Monday - Friday 8:00 am - 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max F Hindenburg can be reached on (703)308-3130. The fax phone numbers for the organization where this application or proceeding is assigned are (703)-308-0758 for regular communications and (703)-308-0758 for After Final communications.


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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)-308-0858.



JMLF

June 4, 2003



**MAX F. HINDENBURG**  
**SUPERVISORY PATENT EXAMINER**  
**TECHNOLOGY CENTER 3700**